

REMARKS

Prior to this Response, claims 1-21 were pending in this application. Claims 1-3 and 11-21 were withdrawn under a restriction requirement. Claims 4-9 have been amended, leaving claims 4-10 remaining. These amendments do not introduce new matter within the meaning of 35 U.S.C. §132. Basis for the amendments is found on page 5, line 21 to page 6, line 24; in Examples 2-4; in Tables 2 and 3; in claims 1-21 as originally filed; and elsewhere throughout the specification and claims. Accordingly, entry of the amendments is respectfully requested.

1. Objection to the Claims

The Office Action objects to the claims for the following reasons:

Claims 4-10 are objected to because of the following informalities:

Accession number(s) of the yeast strain as intended for the claimed invention are missing. Appropriate correction is required.

It is respectfully submitted that the amendment to insert the accession number MTCC 5155 obviates this objection.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the objection to the claims.

2. Rejections under 35 U.S.C. §112, first paragraph

The Office Action rejects claims 4-10 under 35 U.S.C. § 112, first paragraph, as lacking enablement relating to the deposit of biological samples, and states the following:

At least some of the claims require one of ordinary skill in the art to have access to specific yeast strain(s) belonging to the species of *Candida versatilis*. Because the microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public.

Applicants acknowledge the need for a deposit of biological materials in this instance. In accord with 37 CFR §1.804(b) and 1.809(), upon the application otherwise being in condition for allowance, Applicants will provide full compliance with the deposit and availability requirements of 37 CFR §1.801, et seq.

37 CFR §1.809(b) states the requirements for responding to a rejection requiring a deposit:

"The applicant for patent or patent owner shall reply to a rejection under paragraph (a) of this section by ...
(1) In the case of an applicant for patent, either making an acceptable original, replacement, or supplemental deposit, or assuring the Office in writing that an acceptable deposit will be made prior to payment of the issue fee."

Applicants hereby assure the Examiner that, upon the application otherwise being in condition for allowance, documentation of an acceptable deposit will be made prior to payment of the issue fee, in accord with 37 CFR §1.809(d).

Further, Applicants request that this application be treated

under the procedure outlined in 37 CFR §1.809(c) and (e):

"If an application for patent is **otherwise in condition for allowance except for a needed deposit** and the Office has received a written assurance that an acceptable deposit will be made, applicant will be notified and given a period of time within which the deposit must be made in order to avoid abandonment.

* * *

Any amendment required by paragraphs (d)(1), (d)(2) or (d)(4) of this section must be **filed before or with the payment of the issue fee** (see §1.312)." (emphasis added)

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection, subject to Applicants meeting the requirements of 37 CFR §1.801, et seq.

3. Rejections under 35 U.S.C. §112 for Indefiniteness

The Office Action rejects claims 4-10 under 35 U.S.C. § 112, second paragraph, for the following reasons:

Claim 4 is indefinite and incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: accession number of the yeast strain as intended.

Further, claim 4 is confusing with respect to antecedent basis as related to the use of "mutated strain", "yeast mutants", "permeabilized yeast mutants".

Claim 5 as written appears to lack an antecedent basis for the active step of permeabilizing in the method of claim 4.

Claims 7-9 recite phrases "highest" and "maximum" that are terms of relative degree. The metes and bounds of these terms cannot be determined.

The foregoing claim amendments obviate these rejections. In

particular, Applicants have amended claim 4 to insert the accession number, to make clear that the claim applies to "a mutated, permeabilized strain *Candida versatilis* MTCC 5155", and to provide clearer antecedent basis "permeabilizing" in claim 5; and have amended claims 7-9 to remove all terms which are arguably of relative degree.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

4. Rejection of Claims 4-10 under 35 U.S.C. §103(a)

The Office Action rejects claims 4-10 under 35 U.S.C. §103(a) as being unpatentable over US 4,794,014 (Siren), Quan et al. ("Production of phytase in a low phosphate medium by a novel yeast *Candida krusei*". Journal of Bioscience and Bioengineering. 2001. Vol. 92, No. 2, pages 154-160) and Bindu et al. ("A comparative study on permeabilization treatments for in situ determination of phytase of *Rhodotorula gracilis*". Letters in Applied Microbiology. 1998. 27:336-340). As the basis for this rejection, the Office Action states, in relevant part:

... US 4,794,014 (Siren) discloses a method for reducing phytic acid level in food preparations made from phytate-containing materials (IP6 materials) by using yeast cells as a source of phytase (entire document including col. 3, lines 50-65 and col. 5, lines 22-24). ... The yeast culture that is used as a source of phytase is generic and/or belongs to baker's yeast or *Saccharomyces*. Thus, the cited patent is lacking particular disclosure about the use of yeast cells belonging to *Candida*.

... Quan et al. demonstrates that yeast cells belonging to *Candida* produce high level of phytase (abstracts) and they are capable of biodegrading phytate in food materials including wheat.

The cited documents US 4,794,014 (Siren) and Quan et al. demonstrate that yeast cells are source of phytase but they are silent about preliminary treatments of yeast cells that are used as source of phytase in the methods for reducing phytic level in food preparation including wheat and/or wheat-containing dough.

However, the reference by Bindu et al. teaches that yeast cells have tough cell walls, that permeabilization treatments provide for a larger amount of released enzymes and that repeated cycles of freeze-thawing are most efficient for enhancing phytase activity in yeast cell preparations (entire document including abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify method for reducing phytic acid level taught by US 4,794,014 (Siren) by using yeast cells belonging to *Candida* with a reasonable expectation of success in reducing phytic acid level in wheat containing food including dough or "Chapathi dough" because it is well known that yeast cells are used for enzymatic reduction of phytic acid levels in various food and that yeast cells belonging to *Candida* are source of phytase having high enzymatic activity. One of skill in the art would have been motivated to enhance enzymatic activity of yeast cell preparations by permeabilizing yeast cells through repeated freeze-thaw cycles for the expected benefits in increasing levels of phytate biodegradation.

RESPONSE

Applicants respectfully traverse this rejection. To establish a *prima facie* case, the PTO must satisfy three requirements. First, the prior art reference must teach or suggest all the limitations of the claims. *In re Wilson*, 424 F.2d 1382, 1385, 165

U.S.P.Q. 494, 496 (C.C.P.A. 1970). Second, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Third, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991). In this instance, the cited references, alone and in combination, fail to teach or suggest all the limitations of the claims, and thus fail to establish a *prima facie* case of obviousness.

The presently claimed subject matter relates to a method of using a mutated, permeabilized strain *Candida versatilis* MTCC 5155 in optimizing the making of traditional *Chapathi* dough, by improving the process of reducing phytic acid and increasing the bioaccessibility of nutrients, thus improving the nutritional value of the *Chapathi*.

In contrast, the Siren patent discloses only a general method for reducing phytic acid level in food preparations using a source of phytase which "is generic and/or belongs to baker's yeast or *Saccharomyces*." Thus, as the Examiner admits, the Siren patent is lacking particular disclosure about the use of yeast cells

belonging to the genus *Candida*.

The Examiner cites Quan, et al. to attempt to remedy this deficiency in the cited art. Quan, et al. teach only generically that yeast cells belonging to the genus *Candida* produce high level of phytase and are capable of biodegrading phytate in food materials including wheat. Further, the Examiner admits that even taken together, the cited documents are silent about preliminary permeabilization treatments of yeast cells.

To remedy this additional deficiency in the cited art, the Examiner further cites Bindu, et al. as teaching that permeabilization treatments provide for a larger amount of released enzymes and that repeated cycles of freeze-thawing are most efficient for enhancing phytase activity in yeast cell preparations.

Taken together, the cited references at best teach the generic state of the art prior to the present invention. As discussed above, the claimed subject matter relates to an improvement on the prior art, the use of mutant *Candida versatilis* strain MTCC 5155. The cited references do not teach or suggest either: (1) generally, the use yeast strains of the **species** *Candida versatilis*, nor (2) specifically the particular mutant strain MTCC 5155.

The claimed subject matter relates to a selection invention which is an improvement over the prior art. The cited references, and indeed the art as a whole as known to Applicants, does not

teach or suggest to one of ordinary skill in the art that an improved strain could or should be developed from the particular species *Candida versatilis*, or how one would go about developing a mutant *Candida versatilis* strain with the characteristics of increased phytase production and enhanced enzymatic activity. Further, the cited references, and the art as a whole as known to Applicants, does not teach or suggest the claimed mutant strain MTCC 5155.

Thus, in the absence of any teaching or suggestion in the cited references, alone or in combination, that an improved method of reducing phytic acid in food would use yeast strains of the species *Candida versatilis*, as distinguished from the genus *Candida*, and specifically would use the mutant strain MTCC 5155, the claims of the present application cannot be obvious over the cited art.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

CONCLUSION

Based upon the above remarks, the presently claimed subject matter is believed to be clear and definite, fully enabled, and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the rejections of remaining claims 4-10 and allow all

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pending claims presented herein for reconsideration. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.

Respectfully submitted,

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